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DATE MAILED: 12/09/2003

FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. 687-456 Boaz Harari 1856 11/12/2001 10/005,760 EXAMINER 7590 12/09/2003 JEFFREY J. HOHENSHELL PHILOGENE, PEDRO AMERICAN MEDICAL SYSTEMS ART UNIT PAPER NUMBER 10700 BREN ROAD WEST MINNETONKA, MA 55343 3732

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary		Application No.	Applicant(s)	
		10/005,760	HARARI ET AL.	
		Examiner	Art Unit	
		Pedro Philogene	3732	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status				
1)⊠	Responsive to communication(s) filed on 08 0	<u> October 2003</u> .		
2a)□	This action is <b>FINAL</b> . 2b)⊠ This	action is non-final.		
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims				
4)⊠	4)⊠ Claim(s) <u>1-4,10,11 and 15-28</u> is/are pending in the application.			
•	4a) Of the above claim(s) is/are withdrawn from consideration.			
5)	Claim(s) is/are allowed.			
6)⊠	Claim(s) <u>1-4,10,11 and 15-28</u> is/are rejected.			
7)	7) Claim(s) is/are objected to.			
8)□	8) Claim(s) are subject to restriction and/or election requirement.			
Application Papers				
9) The specification is objected to by the Examiner.				
10)☑ The drawing(s) filed on ॎऻॣ॔ॳॣॳॖis/are: a)☑ accepted or b)☐ objected to by the Examiner.				
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority under 35 U.S.C. §§ 119 and 120				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.  37 CFR 1.78.  a) The translation of the foreign language provisional application has been received.  14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.				
Attachment(s)				
2) Notice	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)	

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### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language " a force on aid handle in a particular direction is higher than a predetermined amount" is so unclear, that it renders the claims indefinite. It is not clear to what amount the applicant is referring.

In claim 11, line 6, the term "said predetermined force" lacks prior antecedent basis. In claim 11, the last paragraph should be deleted.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Romano (5,509,918).

With respect to claim 15, Romano discloses a self-aligning device for boring into bone, comprising a boring head (234) having at least two boring tips (240) a body (182,184) a handle (20) attached to the body a hinge (242,246) coupling the head to the body at a location substantially equidistant from the boring tips; as best seen in 8.

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With respect to claims 16-19, Romano discloses all the limitations, as set forth in columns 12.13.14 lines 1-67; and as best seen in FIGS 8-9C.

Claims 20-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Sohn (WO/97/47246)

With respect to claims 20-22, Sohn discloses a method for boring a channel in a bone, comprising the steps of providing a device (40) capable of drilling a hole in bone and of advancing a needle (20) drilling two holes in a cortex of the bone with the device; and using the device to advance at least one needle (20) through the drilled holes through a medulla of the bone; as set forth in the abstract; and, as best seen in FIG.6.

With respect to claim 23, Sohn discloses an apparatus for forming a channel in a bone comprising: at least one drill bit, as set forth in the abstract; for drilling into a bone and detecting a channel formed therethrough and an aperture from the outside of the bit to the channel; as best seen in FIG.9D; and, at least one needle (140) adapted to fit through the aperture.

With respect to claim 24-28, Sohn discloses all the limitations, as set forth in page 15, lines 1-37; as set forth in the abstract; and, as best seen in FIGS: 1-13.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>(</sup>a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 1-4,10,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romano (5,509,918) in view of Sohn (WO97/47246).

With respect to claims 1-4,10,11 Romano discloses a bone boring device; as best seen in the figures, comprising: at least one cutting bit (234,240) adapted for boring into bone a force providing element (100,102,182,184) remote from the cutting, for advancing the cutting bit; and a force amplifier (230,244) coupled to the cutting bit and adjacent to the cutting which amplifies force provided from the force providing element and supplies it to the cutting bit (234,240).

With respect to claims 2-4, Romano discloses all the limitations; as set forth in column 5, lines 50-67, column 6, lines 1-67; columns 7,8, lines 1-67; columns 12,13, lines 15-67; column 14, lines 1-40.

With respect to claims 10,11, Romano discloses a bone-boring device comprising at least one curved cutting bit (234,240) adapted for extending to bore a hole in a bone, a base (174) holding the cutting bit and adapted for being placed against a bone; a handle (20) coupled to the base, and a needle retractor (100,102,182,244) which retracts the needle when a force on the handle in a particular direction is lower than a predetermined amount prior to the base retreating from the bone in response to a lowering of the force; as set forth in columns 6-9, lines 1-67; and a cutting bit advancer (100,102,182,244) which advances the cutting bit only when a force on the handle in a particular direction is higher than a predetermined amount the predetermined force assuring that the base is urged against the bone; as set forth in columns 6-9, lines 1-67.

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It is noted that Romano did not teach of a needle for boring into bone; as claimed by applicant. However, in a similar art, Sohn evidences the use of a curved needle for boring into a bone so that as the needle creates the hole no bone is caused to chip or break near the site of the hole.

Therefore, given the teaching of Sohn, and since Sohn taught the use of either the needle alone or a drill bit to create the hole, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the curved bit of Romano with the needle as taught by Sohn so that as the needle creates the hole no bone is caused to chip or break near the site of the hole.

## Response to Amendment

Applicant's arguments with respect to claims 1-4,10,11, 20-28, have been considered but are most in view of the new ground(s) of rejection.

In response to applicant argument's with respect to claims 15-19 that a substantially equal force is applied to the boring tips, nowhere in the claim there is such a limitation. Applicant is claiming a hinge coupling .... At a location equidistant from the boring tips, to that effect applicant's attention is directed to Romano FIG.9A., where the boring tips are equidistant from the hinge.

#### Conclusion

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703)

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308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene December 05,2003

PEDRO PHILOGENE PRIMARY EXAMINER